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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TODD CAMPBELL

Appeal 2008-4192
Application 10/056,418
Technology Center 1600

Decided: September 24, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and RICHARD M.
LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a stent assembly. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

BACKGROUND

“Stents have been developed with coatings to deliver drugs or other therapeutic agents” (Spec. 1). “Alternative strategies for delivering

drugs or other therapies at the site of the stent have included sheaths enclosing all or almost all of the stent” (*id.* at 2). “Problems can arise if the sheath covers side branch arteries, vessels, or other lumens extending from the main lumen in which the stent is installed. The sheath can reduce blood flow to or from the side branch and deliver medication into the side branch where it is unnecessary” (*id.* at 2). The Specification discloses that it “would be desirable to have a stent assembly with exterior banding for delivery of therapeutic agents that would overcome the above disadvantages” (*id.* at 5).

DISCUSSION

1. CLAIMS

Claims 34-36, 38, and 42 are on appeal. Claims 10-33 are also pending but have been withdrawn from consideration by the Examiner (App. Br. 5).

Claim 34 is representative and read as follows:

Claim 34: A stent assembly for implantation in a body lumen comprising:
a stent; and

a plurality of bands circumferentially wrapped around the stent, the plurality of bands including at least a first band and a second band, the width of each of the bands being substantially less than the diameter of the stent;

wherein the bands further comprise a polymer containing a therapeutic agent, the bands elastically gripping the stent; and

wherein individual bands of the plurality of bands contain different therapeutic agents, the first band containing a first therapeutic agent and the second band containing a second therapeutic agent, the first therapeutic agent being different than the second therapeutic agent.

2. OBVIOUSNESS

Claims 34-36, 38, and 42 stand rejected under 35 U.S.C. § 103 as obvious in view of Layne¹ and Ragheb.²

The Examiner relies on Layne as disclosing “a stent assembly . . . including: a stent 30, a plurality of bands 52 circumferentially wrapped around the stent, where the plurality of bands include at least [a] first and [a] second band . . . , where the bands elastically can grip the stent” (Ans. 3). The Examiner further finds that “Layne is silent regarding the bands contain[ing] different therapeutic agents” (*id.*).

The Examiner relies on Ragheb as disclosing that “the stent has different therapeutic agents” (*id.*). The Examiner concludes that it “would have been obvious to one having ordinary skill in the art . . . to modify Layne by making the bands contain different therapeutic agents as taught by Ragheb in order to facilitate different treatment . . . using different therapeutic agents at the stent site” (*id.*).

Appellant argues that the cited references do not teach the claim limitation of a band that comprises a polymer containing a therapeutic agent (App. Br. 11). Specifically, Appellant argues that Layne discloses a series of spaced apart circumferential bands made of ePTFE (expanded polytetrafluoroethylene; Layne, ¶ 0006) but is silent regarding the bands containing any therapeutic agent (*id.* at 11-12) and that Ragheb also “fails to disclose a band comprising a polymer containing a therapeutic agent” (Reply Br. 6).

¹ Layne, US 2001/0020181 A1, Sep. 6, 2001.

² Ragheb et al., U.S. Patent 6,096,070, Aug. 1, 2000.

Appellant also argues that the cited references do not teach the claim limitation of a band “elastically gripping the stent” (App. Br. 12). Specifically, Appellant argues that “the ePTFE material, which is the only band material disclosed in the *Layne* application, is inelastic and ...incapable of gripping the stent” (*id.*). In support, Appellant cites Layne’s disclosure that “[r]adial expansion of a stent may stress and tear an ePTFE cover” (*id.*, citing Layne, ¶0007).

We agree with Appellant that the cited references do not support a prima facie case of obviousness. In particular, we agree that the Examiner has not adequately explained how the references would have suggested a band that comprises a polymer containing a therapeutic agent or that elastically grips the stent.

Layne discloses “partially encapsulat[ed] stents wherein flexibility of the stent is retained, despite encapsulation. This can be done by placing a plurality of longitudinal strips over the stent or series of stents rings made of ePTFE and/or placing a plurality of circumferential ePTFE bands over the stent(s)” (Layne, ¶0008). Layne discloses that ePTFE “is light and porous and is readily colonized by living cells so that it becomes a permanent part of the body” (*id.* at ¶0006).

Ragheb discloses a “vascular stent or other implantable medical device that provides a controlled release of an agent, drug or bioactive material” (Ragheb, col. 3, ll. 8-10). The device comprises “a base material; at least one layer of a bioactive material posited on one surface of the structure . . . ; and at least one porous layer posited over the bioactive material layer . . . , the porous layer being composed of a polymer and

having a thickness adequate to provide a controlled release” (*id.* at col. 3, ll. 27-38). Ragheb also discloses that “the bioactive material lies under the at least one porous layer **20**, rather than being dispersed within or throughout it” (*id.* at col. 10, ll. 58-60).

Thus, Layne does not disclose a therapeutic agent as part of a stent (as acknowledged by the Examiner), and Ragheb specifically discloses that the bioactive material lies under the porous layer (i.e., polymer), rather than being dispersed within or throughout it. We agree with Appellant that the Examiner has not adequately explained how the combination of Layne and Ragheb would have suggested the limitation of bands that comprise “a polymer containing a therapeutic agent,” as required by the claims on appeal, to one of ordinary skill in the art.

Further, Layne discloses only ePTFE for the composition of the bands, and the Examiner has not provided any evidence to establish that ePTFE is an elastic material. We therefore agree with Appellant that the Examiner has not adequately explained how the combination of Layne and Ragheb would have suggested the limitation of a band that “elastically grip[s] the stent,” as required by the claims on appeal, to one of ordinary skill in the art.

We therefore agree with Appellant that the Examiner has not made out a prima facie case of obviousness based on the cited references.

REVERSED

Ssc:

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